IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Moriwaki et al.	Examiner:	Larry R. Wilson
Serial No.:	10/551,898	Group Art Unit:	3767
Filed:	January 5, 2006	Docket No.:	10873.1788USWO
Title:	MEDICAL NEEDLE DEVICE WITH WINGED SHIELD		

CERTIFICATE OF TRANSMISSION
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APPELLANTS' BRIEF ON APPEAL

Dear Sir:

This Brief is presented in support of the Notice of Appeal filed February 23, 2010, from the final rejection of claims 1 and 4-7 of the above-identified application, as set forth in the Office Action mailed November 23, 2009.

Please charge our Deposit Account No. 50-3478 in the amount of $540.00 to cover the required fee for filing this Brief.

I. REAL PARTY IN INTEREST

The application pending for this appeal has been assigned to JMS CO. LTD., of Hiroshima, Japan.

II. RELATED APPEALS AND INTERFERENCES

The Assignee, the Assignee's legal representatives, and the Appellants are unaware of any other appeals or interferences that will affect, be directly affected by or have a bearing on the Board's decision in this Appeal.

III. STATUS OF CLAIMS

Claims 1 and 4-7 are pending. Claims 1 and 4-7 are rejected and are the subject of this Appeal. Claims 2 and 3 were canceled during prosecution. Appendix A attached herewith provides a copy of the claims in this Appeal.

IV. STATUS OF AMENDMENTS

No Amendments have been filed subsequent to the November 23, 2009 final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1, the sole independent claim in this application, is directed to a medical needle device with a winged shield 4. The device of claim 1 requires a winged shield 4 that has a substantially cylindrical shield tube 4a and a pair of wings 5, 6 positioned at a front end side of the shield tube 4a (see, e.g., page 4, line 29 to page 5, line 4 of the specification and Fig. 1). The device also requires a hub 2 that is inserted into an inner bore of the shield tube 4a so as to be movable in an axial direction (see, e.g., page 5, lines 4-6 of the specification and Fig. 1). The device also requires a needle 1 that is mounted to a front end of the hub 2 (see, e.g., page 4, line 30 to page 5, line 1 and Fig. 1). The device further requires an infusion tube 3 connected to a rear end of the hub 2 (see, e.g., page 5, lines 1-2, page 14, lines 6-8 of the specification and Fig. 1).

A tip of the needle 1 is capable of being stored in the inner bore of the shield tube 4a (see, e.g., page 7, lines 16-18 and Fig. 3). At least a part of the hub 2 is made of a material having flexibility (see, e.g., page 5, lines 13-14). The needle 1 is inserted into and coupled with a bore of the hub 2 at the front end thereof (see, e.g., Figs. 2, 3). The rear end portion of the hub 2 is inserted into and coupled with the infusion tube 3 (see, e.g., Figs. 2, 3). The shield tube 4a

and the hub 2 are bendable together at least in a part of a range along an axial direction when the needle 1 protrudes from the front end of the shield tube 4a and is latched to the shield tube 4a so as to be in a puncturing position (see, e.g., page 5, lines 17-18 and Figs. 1-3).

The advantageous effects of the present medical needle device are explained as follows. The present hub helps retain and position the needle inside the shield tube by holding the needle with the hub and further makes it easy to connect the needle with an infusion tube through the hub (see, e.g., page 4, lines 2-5 of the specification). When the needle protrudes from a front end of the shield tube and is inserted in the patient's body, as shown, for example, in Fig. 1, both the shield tube and the hub may be bent and secured to the patient's body. This bendable feature of the shield tube and hub allows the needle device to be bent at a position that is sufficiently close to the needle so that the rest of the needle device can be moved away to make it easy for an additional needle to be inserted (see, e.g., page 4, lines 2-8 of the specification).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following issue is raised in the final rejection:

- Whether claims 1 and 4-7 are unpatentable over Teraoka (EP 1 048 311) in view of Whisson (US 5,762,632) and more particularly:

  A. whether Teraoka or Whisson teaches or suggests all of the features of claim 1;
  B. whether the discussion of "the movement of the engaging means to the retracted position may cause a destructive bending or 'kinking' of the delivery tube to render the infusion set incapable of further use" in Whisson would suggest including the flexible delivery tube and the flexible duct of Whisson as a hub and a shield tube, respectively, in the injection needle of Teraoka.

VII. ARGUMENT

Claims 1 and 4-7 are patentable over Teraoka (EP 1 048 311) in view of Whisson (US 5,762,632) because the combination of Teraoka and Whisson at least fails to teach or suggest the invention of claim 1.

Claims 1 and 4-7 are rejected under 35 USC § 103(a) as being unpatentable over Teraoka (EP 1 048 311) in view of Whisson (US 5,762,632). Appellants respectfully request reversal of the rejection for at least the following reasons. For purposes of this appeal only, independent claim 1 is argued below and the dependent claims 4-7 are considered to stand or fall together with claim 1.

A. Teraoka and Whisson, taking alone or together, fail to teach or suggest all of the features of claim 1.

Claim 1 requires a shield tube and a hub to be bendable together at least in a part of a range along an axial direction when a needle protrudes from a front end of the shield tube and is latched to the shield tube so as to be in a puncturing position.

The present hub helps retain and position the needle inside the shield tube by holding the needle with the hub and further makes it easy to connect the needle with an infusion tube through the hub. When the needle protrudes from a front end of the shield tube and is inserted in the patient's body, as shown, for example, in Fig. 1, both the shield tube and the hub may be bent and secured to the patient's body. This bendable feature of the shield tube and hub allows the needle device to be bent at a position that is sufficiently close to the needle so that the rest of the needle device can be moved away to make it easy for an additional needle to be inserted.

Teraoka is directed to an injection needle device 1 that includes an injection needle 2, a cylindrical holder 3 tightly fixing the injection needle 2, a tube 4 through which a liquid medicine can flow, a cylindrical connector 5 connecting the holder 3 and the tube 4, a stretchable member 6 having an accordion structure, and a protector 8 having a pair of wings 7 at both sides, where a liquid medicine passageway extends through the cavity of the stretchable member 6 and the protector 8 (see Teraoka, col. 4, lines 43-58 and Fig. 1). The stretchable member 6 is capable of stretching or contracting in an axial direction to allow the injection needle 2 to be contained in the protector 8 or exposed from the protector 8 (see Teraoka, col. 5, lines 24-37 and Fig. 1).

Teraoka discusses the holder 3 being fitted into a through hole of the connector 5 and the tube 4 being fitted onto the outside of the connector 5 (see Teraoka, col. 5, lines 1-3 and Fig. 1). As a result, when in use, the user can hold the tube 4 and apply a forward insertion force on the tube 4 to insert the injection needle 2 into the body of the patient, where the forward insertion force is transferred from the tube 4 to the holder 3 through the connector 5 and then to the injection needle 2 through the holder 3 (see generally Teraoka, col. 4, line 43-col. 5, line 37 and Fig. 1).

On the other hand, Whisson is directed to an infusion set including a base 11 having a central tubular member 15 with a pair of lateral wing members 16 mounted thereto, a needle 12, and a flexible delivery tube 13 received within a flexible duct 23 for delivering medicine to the needle 12 (see Whisson, col. 2, lines 35-40 and Fig. 1). When in use, the user holds the base to insert or remove the needle 12 into or from the body of the patient (see Whisson, col. 4, lines 46-49 and Fig. 1).

The rejection refers to the Teraoka protector 8 and holder 3 as suggesting the shield tube and hub of the invention of claim 1, respectively (see Office Action, lines 9 and 11 from the bottom of page 2). While acknowledging that Teraoka does not teach a shield tube and a hub being bendable together at least in part of a range along an axial direction when the needle protrudes from the front end of the shield tube and is latched to shield tube, the rejection relies on the flexible duct 23 and flexible delivery tube 13 of Whisson as suggesting a shield tube and a hub being bendable together as required by claim 1 (see Office Action, lines 1-4 from the bottom of page 2 and lines 1-6 on page 3).

Appellants respectfully contend that the rejection is not proper because modification of the Teraoka protector 8 and holder 3 with the Whisson flexible duct 23 and flexible delivery tube 13 would render Teraoka inoperable for its intended purpose.

When a 35 USC 103 rejection is based upon a modification of a reference that destroy the intent, purpose or function of the invention disclosed in the reference, such a proposed modification is not proper and the prima facie case of obviousness cannot be properly made (see *In re* Gordon, 733 F.2d 900, 902; 221 USPQ 1125, 1127 (Fed. Cir. 1984)).

As illustrated in Fig. 1 of Teraoka, the protector 8 does not appear to be bendable, let alone being bendable together with the holder 3. The injection needle 2 extends from a front end

of the holder 3 through an internal space of the protector 8 and out of an opening 11 at the front end of a protector tip 10. Even assuming arguendo the protector 8 is bendable, modifying the protector 8 and the holder 3 to make them bendable together would cause the injection needle 2 to bend and as a result render the injection needle device 1 inoperable for its intended purpose.

Moreover, modification of the Teraoka holder 3 with the Whisson flexible delivery tube 13 would not allow an effective and precise control of the Teraoka injection needle 2 during insertion or removal of the injection needle 2.

As clearly discussed in Teraoka, the opening 11 of the protection tip 10 has to be large enough to allow the injection needle 2 to slide freely (see Teraoka, col. 7, lines 4-7 and Fig. 1). That means the pair of wings 7 along with the protector 8 are axially movable relative to the injection needle 2 and would not provide an adequate axial force to effect insertion or removal of the injection needle 2. As a result, the user has to hold on the tube 4 to insert the injection needle 2 into or remove it from the body of the patient. During this process, the holder 3 acts to help transfer the axial force from the tube 4 to the injection needle 2.

On the other hand, Whisson discusses that the user holds the central tubular member 15 and the wing members 16 of the base 11 to insert or remove the needle 12 into or from the body of the patient, while the flexible delivery tube 13 and the flexible duct 23 are used for delivering medicine to the needle 12.

Modification of the Teraoka holder 3 with the Whisson flexible delivery tube 13 would not permit the axial force applied to the tube 4 to be adequately transferred to the injection needle 2 in Teraoka. Because of the flexibility of the Whisson delivery tube 13, the user could not effectively and precisely manipulate the injection needle device 1 to effect insertion or removal of the injection needle 2 in Teraoka. As a result, the Teraoka injection needle device 1 would be rendered inoperative for its intended purpose.

For at least these reasons, Teraoka and Whisson, taking alone or together, fail to teach or suggest all of the features of claim 1.

B. The discussion of "the movement of the engaging means to the retracted position may cause a destructive bending or 'kinking' of the delivery tube to render the infusion set incapable of further use" in Whisson would not suggest

including the flexible delivery tube and the flexible duct of Whisson as a hub and a shield tube, respectively, in the injection needle of Teraoka.

The rejection refers to the discussion of "the movement of the engaging means to the retracted position may cause a destructive bending or 'kinking' of the delivery tube to render the infusion set incapable of further use" in Whisson as suggesting the use of the flexible delivery tube 13 and the flexible duct 23 of Whisson as a hub and a shield tube, respectively, in the injection needle 2 of Teraoka (see Office Action, page 3, lines 7-11). Appellants respectfully contend that this discussion would by no means suggest the use of Whisson delivery tube 13 and duct 23 in Teraoka.

Whisson discusses a housing 14 including a slider (engagement means) 27 associated with a control knob 28, whereby the knob 28 may be manipulated to cause slidable movement of the slider (engagement means) 27 within the housing 14 (see Whisson, col. 3, lines 19-30 and Figs. 2-3). When the slider (engagement means) 27 is in an extended position, the pathway in the housing 14 for the delivery tube 13 is arcuate and no kinks are induced in the delivery tube 13 (see Whisson, col. 3, lines 42-50 and Figs. 2-5). When the slider (engagement means) 27 is in a retracted position, the delivery tube 13 accommodated within the duct 23 is drawn into the interior of the housing 14, which consequently causes the movement of the needle 12 into the tubular portion 15 of the base 11 (see Whisson, col., 3, lines 51-61 and Figs. 2-3). This enables retraction of the needle 12 into the tubular portion 15 so that a free end 18 of the needle 12 is covered (see Whisson, col., 3, lines 51-63 and Figs. 2-3).

Col. 4, line 61 to col. 5, line 3 of Whisson discusses that "the movement of the engaging means to the retracted position may cause a destructive bending or 'kinking' of the delivery tube to render the infusion set incapable of further use." As a result, in the event of inadvertent movement of the slider (engagement means) from the retracted position to the extended position, the delivery tube can fold up or "kink" rather than causing movement of the needle to the extended position (see Whisson, col. 4, line 64 to col. 5, line 3).

The discussion of "the movement of the engaging means to the retracted position may cause a destructive bending or 'kinking' of the delivery tube to render the infusion set incapable of further use" in Whisson focuses on how the engagement means retract to bend or kink the delivery tube to avoid the exposure of the needle upon inadvertent movement of the engagement

means. This would by no means suggest including the flexible delivery tube 13 and the flexible duct 23 of Whisson as a hub and a shield tube, respectively, in the injection needle 2 of Teraoka.

Accordingly, for at least the above reasons, claim 1 is patentable over Teraoka and Whisson, taken alone or together. Claims 4-7 are also patentable over the references since they depend from claim 1 that is allowable. Reversal of the rejection is respectfully requested.

VIII. CONCLUSION

Appellants submit that the rejections of claims 1, 4-12 and 14-26 are untenable for the reasons set forth above and should be reversed.

Please charge any additional fees or credit any overpayment to Hamre, Schumann, Mueller & Larson Deposit Account No. 50-3478.

Respectfully submitted,

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APPENDIX A - PENDING CLAIMS

1. (Previously presented) A medical needle device with winged shield, comprising:

a winged shield that has a substantially cylindrical shield tube and a pair of wings positioned at a front end side of the shield tube;

a hub that is inserted into an inner bore of the shield tube so as to be movable in an axial direction;

a needle that is mounted to a front end of the hub; and

an infusion tube connected to a rear end of the hub,

a tip of the needle being capable of being stored in the inner bore of the shield tube,

wherein at least a part of the hub is made of a material having flexibility,

the needle is inserted into and coupled with a bore of the hub at a front end thereof and the rear end portion of the hub is inserted into and coupled with the infusion tube, and

the shield tube and the hub are bendable together at least in a part of a range along an axial direction when the needle protrudes from the front end of the shield tube and is latched to the shield tube so as to be in a puncturing position.

2-3. (Canceled)

4. (Previously presented) The medical needle device according to claim 1, wherein the shield tube is made of a material having flexibility.

5. (Previously presented) The medical needle device according to claim 1, wherein the shield tube includes an extendable portion that is structured to be extendable and contractible, the needle can be moved in the axial direction of the shield tube by extending and contracting the extendable portion, and the shield tube and the hub are bendable at the extendable portion.

6. (Original) The medical needle device according to claim 5, wherein the extendable portion has a plasticity-processed accordion-like structure.

7. (Original) The medical needle device according to claim 1, wherein, when the shield tube and the hub in the inner bore of the shield tube are bent together, a minimum radius of curvature at a bent part can be 3 mm or smaller.

APPENDIX B - EVIDENCE

None

APPENDIX C - RELATED PROCEEDINGS

None